

REMARKS

Outstanding Rejections

Claims 1, 2, 4, 5, 8-18 and 20-24 stand rejected under 35 U.S.C. § 103(a) as being obvious over Frey II (U.S. Patent Application Publication No. 2003/0072793) in view of Beers (The Merck Manual of Diagnosis and Therapy, 17th Edition, pp 1525-1539 and pp 1932-1933, 1999).

Claims 1, 2, 4, 5, 8-18 and 20-24 stand rejected under 35 U.S.C. § 103(a) as being obvious over Siuciak (U.S. Patent No. 5,599,560) in view of Beers.

Patentability Arguments

A. The Rejection of Claims 1, 2, 4, 5, 8-18, and 20-24 under 35 U.S.C. § 103(a) over Frey II in view of Beers Should Be Withdrawn

First, Applicants note that the action indicated that claims 1-7, 11-15 and 19-28 were rejected. See page 3, paragraph 8 of the office action. Claims 3, 6-7, 19 and 25-28 were canceled in the previous amendment. Accordingly, the rejections to those claims are moot.

The rejection of claims 1, 2, 4, 5, 8-18 and 20-24 should be withdrawn because Frey II discloses a laundry list of “agents” for the treatment of a laundry list of disorders, but fails to teach or suggest that any one of the recited agents can be used in the treatment of a specific disorder much less those of claim 1.

Frey II discloses the delivery of “agents” to the central nervous system by way of a tissue innervated by the trigeminal nerve that is outside the nasal cavity, and indicates that suitable “agents” can include a lipophilic agent (see paragraph 0040), an organic pharmaceutical (see paragraphs 0041-0043), an inorganic agent (see paragraph 0045), a peptide or protein agent (see paragraph 0046), a peptoid agent (see paragraph 0047), nucleic acid agent (see paragraph 0047) and neurologic agents (see paragraphs 0050-0051).

While Frey II discloses the use of a large list of potential “agents,” one of which is NGF, the disclosure is primarily directed to a mode of administration and does not teach or suggest the use of any particular agent for the treatment of any particular disorder or disease of the CNS. Similarly, paragraph 0168 of Frey II discloses a laundry list of at least seventeen (17) central nervous system (CNS) disorders and disorder types but does not

seventeen (17) central nervous system (CNS) disorders and disorder types but does not specifically disclose the administration of NGF or any of the “agents” described therein for any of the CNS disorders and disorder types discussed therein. Accordingly, one of skill in the art would not know which of the many “agents” disclosed in Frey II could be used for the treatment of, for example, affective disorders. Therefore, one of skill in the art would not be motivated upon review of Frey II to use NGF for the treatment of the psychological disorders recited in independent claim 1, nor would he or she expect NGF to have a beneficial effect with respect to those disorders. Accordingly, there can be no *prima facie* case of obviousness based on Frey II.

Moreover, Frey II provides no disclosure for the use of NGF for the treatment of symptoms associated with the psychological disorder, and especially makes no mention of alleviating the symptoms of sleep disorders, tension headaches, and constipation as recited in independent claim 15.

Beers fails to make up for the deficiencies of Frey II. Beers, a textbook for the diagnosis and therapy of various disorders, teaches that depression is in the same class as affective disorders and that premenstrual syndrome (PMS) is characterized by *inter alia* anxiety and depression. Beers does not teach or suggest the use of NGF for the treatment of depression, anxiety disorders, panic attacks, premenstrual dysphoric disorder (PMDD), and premenstrual syndrome (PMS) or the symptoms associated with those disorders. Considered in combination, Frey II in view of Beers, fails to teach or suggest each element of claims 1, 2, 4, 5, 8-18 and 20-24.

For the foregoing reasons, Applicants submit that the examiner has failed to establish a *prima facie* case of obviousness for the subject matter of any of claims 1, 2, 4, 5, 8-18 and 20-24 under 35 U.S.C. § 103(a) over Frey II in view of Beers. Accordingly, the rejection may properly be withdrawn.

B. The Rejection of Claims 1, 2, 4, 5, 8-18, and 20-24 under 35 U.S.C. § 103(a) over Siuciak in view of Beers May Properly Be Withdrawn

First, Applicants note that the action indicated that claims 1-7, 11-15 and 19-28 were rejected. See page 5, paragraph 12, of the office action. Claims 3, 6-7, 19 and 25-28 were canceled in the previous amendment. Accordingly, the rejections to those claims are moot.

The rejection of claims 1, 2, 4, 5, 8-18 and 20-24 should be withdrawn because Siuciak only teaches the use of specific members of the NGF family of neurotrophins (brain-derived neurotrophic factor (BDNF), neurotrophin-3 (NT-3) and neurotrophin-4 NT-4), but does not teach the use of NGF which is a different protein for the treatment of depression and other psychological disorders. (*See*, for example, column 2, lines 50-52, column 3, lines 36-39, and column 5, lines 6-7). Thus, Siuciak does not teach or suggest the use of NGF for the treatment of depression, anxiety disorders, panic attacks, premenstrual dysphoric disorder (PMDD), and premenstrual syndrome (PMS) as claimed in claim 1 or sleep disorders, tension headaches, and constipation as claimed in claim 15. In fact, Siuciak does not teach or suggest the use of NGF for the treatment of any psychological disorder or any symptoms associated with said psychological disorder. Accordingly, there can be no *prima facie* case of obviousness based on Siuciak.

Beers fails to make up for the deficiencies of Siuciak. Beers, a textbook for the diagnosis and therapy of various disorders, teaches that depression is in the same class as affective disorders and that premenstrual syndrome (PMS) is characterized by *inter alia* anxiety and depression. Beers does not teach or suggest the use of NGF for the treatment of depression, anxiety disorders, panic attacks, premenstrual dysphoric disorder (PMDD), and premenstrual syndrome (PMS) or the symptoms associated with those disorders. Considered in combination, Siuciak in view of Beers, fails to teach or suggest each element of claims 1, 2, 4, 5, 8-18 and 20-24.

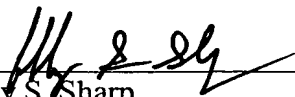
For the foregoing reasons, Applicant submits that the examiner has failed to establish a *prima facie* case of obviousness for the subject matter of any of claims 1, 2, 4, 5, 8-18 and 20-24 under 35 U.S.C. § 103(a) over Siuciak in view of Beers. Accordingly, the rejection may properly be withdrawn.

CONCLUSION

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Dated:

Respectfully submitted,

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